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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/610,313

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Susan Barnett

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NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY- X100B

P.O. BOX 8097

Emeryville, CA 94662-8097

EXAMINER

ANGELL, JON E

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

10/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/610,313	Applicant(s) BARNETT ET AL.	
	Examiner J. E. Angell	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 43-53 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48-51 is/are allowed.
- 6) ☒ Claim(s) 1-40, 43-47, 52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the communication filed on 6/22/2009.

The amendment filed 6/22/2009 is acknowledged and has been entered.

Claims 1-40, 43-53 are currently pending in the application and are addressed herein.

1. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

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Instant claims 1-40 and 43-51 do not enjoy priority to co-pending US application 09/475,704 because application '704 does not provide written support for SEQ ID NO: 30-32, essentially for the reasons of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-40, 43-47, 52, 53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, essentially for the reasons of record.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 1, 5-11, and 19-21 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 16-22, and 30-32 of U.S. Patent No. 7,211,659 (Application No. 10/190,435). Both sets of claims are directed to an expression cassette comprising a polynucleotide sequence encoding an HIV polypeptide and cells comprising the expression cassette. The polynucleotide sequence SEQ ID NO: 9 in the claims of '659 has at least 90% sequence identity to SEQ ID NO: 30-32 in the instant claims. (99.2% sequence identity with SEQ ID NO: 32). Furthermore, the limitations in instant claims 5-11 and 19-21 are the same as the limitations recited in claims 16-22 and 30-32 of the '659 patent.

Response to Arguments

2. Applicant's arguments filed 6/22/2009 have been fully considered but they are not persuasive.
3. Applicants argue that the claims no longer recite "an HIV Pol polypeptide" and that one of skill in the art would clearly understand that were in possession of the currently claimed subject matter.
4. This is not persuasive because, as previously indicated, the Written Description Guidelines for examination indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus."

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(See MPEP 2100-164). In the instant case, the claims are now drawn to a genus of molecules that are at least 90% identical the polynucleotide sequence SEQ ID NO:30, SEQ ID NO:31 or SEQ ID NO:32. The claims no longer indicate that the sequences encode an HIV Pol polypeptide, nor do the claims indicate that the molecules encompassed by the claims have any particular function or activity. Therefore, the instant claims encompass a genus of molecules that are structurally related, but which may be functionally unrelated. As such, the required correlation between function and structure for the claimed genus of molecules has not been provided. It is noted that the only apparent function for the claimed genus of molecules found is as peptides that can generate HIV Pol polypeptide-specific response. It is also noted that the sequences that are SEQ ID NO: 30, SEQ ID NO: 31 and SEQ ID NO: 32 meet the written description requirements, and limiting the claims as such would obviate the instant rejection. However, as previously indicated, the specification does not describe the structural elements of the sequences which are critical for their only apparent function such that one of skill in the art would recognize which sequences less than 100% identical to SEQ ID NO:30, 31 or 32 would be functional and which ones would not, without performing additional experimentation.

With respect to the Double Patenting rejection, Applicants argue that the instant claims are all directed to SEQ ID NO: 30-32 which encode HIV-1 subtype C Protease Reverse-Transcriptase polypeptide, while SEQ ID NO: 9 of the '659 patent is HIV-1 subtype C Gag-Protease Reverse-Transcriptase polypeptide. Applicants contend that SEQ ID NO:9 is clearly different from SEQ ID NO:30-32 because SEQ ID NO:9 includes Gag coding sequence, and that actual identity between the full length SEQ ID NO:9 and SEQ ID NO:32 is only 70%.

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This is not persuasive because claim 1 reads on a polynucleotide sequence that has at least 90% sequence identity to the polynucleotide sequence of SEQ ID NO:30-32. The word "has" is considered open language, and is synonymous with "comprises". Thus, the claim, given its broadest reasonable interpretation, reads on a polynucleotide sequence that comprises at least 90% sequence identity to the polynucleotide sequence of SEQ ID NO:30-32. In other words, claim 1 is not limited to a polynucleotide sequence that is at least 90% identical to the polynucleotide sequence of SEQ ID NO:30, 31 or 32. Rather, claim 1 encompasses any polynucleotides sequence that has within it a sequence that is at least 90% identical to SEQ ID NO: 30, 31 or 32. Thus, SEQ ID NO:9 of the issued patent does "have" at least 90% sequence identity to the polynucleotide sequences of SEQ ID NO:30-32, and thus the rejection is proper. It is noted that amending the claim to change "has at least 90% sequence identity" to "is at least 90% identical" would obviate this rejection.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635